Neurocrine Biosciences Announces Positive Results in Daisy PETAL Study

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PHASE II STUDY MEETS ALL EFFICACY ENDPOINTS

SAN DIEGO, May 24, 2010 /PRNewswire via COMTEX/ --Neurocrine Biosciences, Inc. (Nasdaq: NBIX) today announced statistically significant and clinically meaningful top-line efficacy results from its Phase II Daisy PETAL study (901 study) using its proprietary, orally-active nonpeptide Gonadotropin-Releasing Hormone (GnRH) receptor antagonist, elagolix, in patients with endometriosis.

"The Daisy PETAL study was successful, all primary and secondary efficacy endpoints were met, and provided exactly the information we need to move this program forward," said Chris O'Brien, M.D., Chief Medical Officer at Neurocrine. "We now have confirmation that the daily scales for menstrual and non-menstrual pelvic pain, developed with extensive input from the FDA and patients, function well in a clinical trial setting. These daily endpoints reflect the way women with endometriosis experience their symptoms and also demonstrate improvement with elagolix."

Co-Primary Efficacy and Exploratory Endpoints- Mean Change from Baseline

The top-line data confirm that elagolix is associated with statistically significant reductions in Dysmenorrhea, Non-Menstrual Pelvic Pain, (co-primary endpoints) and Dyspareunia (exploratory endpoint) daily scores when compared to placebo (ITT population, ANCOVA).

Mean Change From Baseline to Week 8	Baseline	Elagolix	Placebo	p-value
Dysmenorrhea	2.1	-1.13	-0.37	<0.001
Non-Menstrual Pelvic Pain	1.4	-0.47	-0.19	<0.01
Dyspareunia	1.4	-0.61	-0.23	<0.01

Efficacy Endpoint- Responder Analyses

At the recommendation of the FDA, responder analyses were also conducted. Significant improvement in all three of the daily scales was evident using a standard threshold for clinically meaningful improvement of 30% or greater reduction from Baseline. The table below displays the percentage of subjects that met the responder definition (ITT population, chi-square).

Responder Analyses Week 8	Elagolix	Placebo	p-value
Dysmenorrhea	63%	33%	<0.001
Non-Menstrual Pelvic Pain	63%	33%	<0.001
Dyspareunia	58%	34%	<0.05

Secondary Efficacy Endpoints

The Patient Global Impression of Change (PGIC) showed a statistically significant improvement for elagolix subjects. On this 1-7 scale, a score of 4 is "no change," 3 is "minimally improved," 2 is "much improved," and 1 is "very much improved." At Week 8 the PGIC percentage of subjects scoring "much improved" or "very much improved" was greater for elagolix (60%) vs. placebo (30%) (p<0.001,ITT population, chi-square).

The Endometriosis Health Profile 5 (EHP-5) assesses the impact of endometriosis-related pain on five daily functions, on a 0-100 scale. The EHP-5 core pain domain score showed considerable improvement for subjects randomized to elagolix. At Week 8 the EHP-5 score was -28 for the elagolix arm compared to -13 for the placebo arm (p <0.001, ITT population, ANCOVA).

The Composite Pelvic Signs and Symptoms Scale (CPSSS), a 0-15 scale, was assessed at screening and Week 8 (Baseline score of 9.5). The reduction from the Baseline score in the CPSSS showed a statistically significant and clinically meaningful improvement with elagolix, -4.5; vs. placebo, -2.2; (p <0.0001, ITT population, ANCOVA).

Safety Profile

Elagolix was generally safe and well tolerated; discontinuation from the clinical trial due to adverse events was low at 4.4% (elagolix) and 1.4% (placebo). The most common adverse event reported more often with elagolix than with placebo was nausea (7.4% elagolix; 2.9% placebo), consistent with previous clinical studies of elagolix. There were no elagolix treatment-related Serious Adverse Events.

"The data from this Daisy PETAL Study allows us to complete our End of Phase II meeting request and finalize the drafting of the Special Protocol Assessment request, both of which we anticipate filing with the FDA in late June," said Kevin C. Gorman, President and Chief Executive Officer of Neurocrine. "These results add to the already strong elagolix clinical data package gathered from the almost 1,000 subjects who have participated in Phase I and II studies to date."

Daisy PETAL Study Design

The US based Daisy PETAL study enrolled 137 endometriosis subjects into one of two treatment groups; elagolix 150 mg or placebo once daily for two months of treatment, in a double-blind design. Subjects are continuing for four months of open-label elagolix treatment and assessments. These top-line efficacy results are based on the ITT population of 132 women.

Co-primary efficacy endpoints of dysmenorrhea (pelvic pain during menstruation) and non-menstrual pelvic pain (pelvic pain outside of menstruation) were evaluated to assess the improvement of endometriosis symptoms following treatment with elagolix. These endpoints were employed based on extensive discussions with the Division of Reproductive and Urologic Products at the FDA; each utilized a daily scale (0-3) via daily electronic diary. Dyspareunia (painful intercourse) was also assessed using a daily scale (0-3) as an exploratory measure. The PGIC, EHP- 5 and the CPSSS were assessed as secondary efficacy endpoints.

Neurocrine Biosciences would like to thank the patients and the investigators for participating in this important clinical trial.

Conference Call and Webcast Information

The Company will host a live conference call and webcast to provide additional details of this study tomorrow, Tuesday May 25, 2010 at 8:30 a.m. Eastern Time (5:30 a.m. Pacific Time). Participants can access the live conference call by dialing 1-800-894-5910 (US) or 785-424-1052 (International) using the conference ID: 7NBIX. The call can also be accessed via the webcast through the Company's website at http://www.neurocrine.com.

If you are unable to attend the Webcast and would like further information on this announcement please contact the Investor Relations Department at Neurocrine Biosciences at (858) 617-7600. A replay of the Conference Call will be available approximately one hour after the conclusion of the call by dialing 1-800-723-0532 (US) or 402-220-2655 (International) using the conference ID: 7NBIX. The call will be archived for two weeks.

Neurocrine Biosciences, Inc. is a biopharmaceutical company focused on neurological and endocrine diseases and disorders. Our product candidates address some of the largest pharmaceutical markets in the world including endometriosis, anxiety, depression, pain diabetes, irritable bowel syndrome, insomnia and other neurological and endocrine related diseases and disorders. Neurocrine Biosciences, Inc. news releases are available through the Company's website via the internet at http://www.neurocrine.com.

In addition to historical facts, this press release may contain forward-looking statements that involve a number of risks and uncertainties. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with Neurocrine's business and finances in general, as well as risks and uncertainties associated with the Company's GnRH program and Company overall. Specifically, the risks and uncertainties the Company faces with respect to the Company's GnRH program include, but are not limited to, risk that the elagolix clinical trials will fail to demonstrate that elagolix is safe and effective; risk that elagolix will not proceed to Phase III clinical trials; risk associated with the Company's dependence on corporate collaborators for Phase III development, commercial manufacturing and marketing and sales activities. With respect to its pipeline overall, the Company faces risk that it will be unable to raise additional funding required to complete development of all of its product candidates; risk relating to the Company's dependence on contract manufacturers for clinical drug supply; risks associated with the Company's dependence on corporate collaborators for commercial manufacturing and marketing and sales activities; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products; and the other risks described in the Company's report on Form 10-K for the year ended December 31, 2009 and reports on Form 10-Q for the quarter ended March 31, 2010. Neurocrine undertakes no obligation to update the statements contained in this press release after the date hereof.

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